

REMARKS

Indefiniteness Rejection

Claims 1, 3-15, and 17 were rejected under 35 USC § 112, second paragraph. (Paper No. 06072005 at 5.) In making the rejection, the Examiner asserted that “[I]nstant claim recites ‘matrix consisting of an emulsion-forming composition selected from ...’, which is indefinite because it is unclear to the examiner if the matrix consists [of] only one of the polymers listed or does it have more components than the polymers. If the latter is true then, the expression ‘consisting of’ is not proper because it is a closed expression limiting to only the polymer.” The Examiner then requested a “clarification and correction.” (*Id.*)

For the reasons set forth below, the rejection is traversed.

To reject a claim under the second paragraph of 35 USC 112, it is incumbent on the Examiner to establish that one of ordinary skill in the pertinent art, when reading the claims in light of the supporting specification, would not have been able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the claims. *Ex parte Wu*, 10 USPQ2d 2031, 2033 (BPAI 1989). This, the Examiner has not done.

Claim 1 recites “a matrix consisting of an emulsion-forming composition selected from the group consisting of a natural polysaccharide gum, a mixture of polysaccharide gums, a protein, a mixture of proteins, and mixtures thereof....” The phrase “consisting of an emulsion-forming composition...” employs the closed term “consisting” just as prescribed by USPTO.

The transitional phrase “consisting of” excludes any element, step, or ingredient not specified in the claim. *In re*

Gray, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("consisting of" defined as "closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith."). ... When the phrase "consists of" appears in a clause of the body of a claim, rather than immediately following the preamble, it limits only the element set forth in that clause; other elements are not excluded from the claim as a whole. *Mannesmann Demag Corp. v. Engineered Metal Products Co.*, 793 F.2d 1279, 230 USPQ 45 (Fed. Cir. 1986).

MPEP §§ 2111.03 (8th ed. Rev. 3, August 2005, pp. 2100-53 to 2100-54). Thus the matrix of the instant claims "consists of" those "emulsion-forming compounds" specifically listed in the Markush group that follows.

Accordingly, one skilled in the art would readily recognize what is being claimed. Nothing more is required, and the Examiner has not articulated any facts to support the rejection. For this reason, the rejection is deficient and should be withdrawn.

Rejection under 35 USC § 102

Claims 1,7-11, and 15 were rejected under 35 USC § 102(b) as anticipated by Finnan, U.S. Patent No. 5,120,761 ("Finnan"). (Paper No. 06072005 at 3.)

For the reasons set forth below, the rejection respectfully is traversed.

Finnan discloses "free-flowing, spray-dried edible powder is preferably made by partially hydrolyzing a gelatin, followed by making an emulsion of the gelatin and an edible oil, followed by spray-drying the emulsion." (Abstract.) The edible oil may be any oil with "nutritional characteristics" and is preferably vitamin E acetate. (Col. 3, lines 36-40.) Example 6 contains the only mention of any size for the particles

of the powder. "About 75% of the powder particles were between 47 and 250 microns."
(Col. 10, lines 12-14.)

In making the rejection, the Examiner asserted that "Finnan discloses a method of making a free-flowing spray dried edible powder comprising oil, wherein the emulsion is made by gelatin and the edible oil is preferably vitamin E. (abstract, col. 3, lines 7-42)." (Paper No. 06072005 at 3.) The Examiner further asserted that Finnan discloses "an example of spray-dried powder comprising vitamin E, gelatin, moisture content etc. (col. 10, lines 1-19) and the powder particles having a size of 74 to 250 microns, which includes the claimed particle sizes." (*Id.*) The Examiner then concluded that "Finnan anticipates instant claims." (*Id.*)

As is well settled, anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply*, 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir 1984).

Initially, we note that claim 1, the sole independent claim, recites "solid droplets having an **average diameter of about 80 to about 120 nanometers**." Contrary to the Examiners assertion the "powder particles having a size of **74 to 250 microns**" disclosed by Finnan does not "include[] the claimed particle sizes." **A micron is millionth of a meter. And, a nanometer is one billionth of a meter.** The particles sizes disclosed by Finnan are from 74,000 to 250,000 nanometers. Accordingly,

Finnan discloses particles sizes between 600- and 3,100-times greater than those recited in claim 1.

Clearly, Finnan does not disclose each and every element of the claimed invention. For this reason, the rejection is insufficient and should be withdrawn.

Rejections under 35 USC § 103

Claims 12-14 were rejected under 35 USC § 103(a) as being unpatentable over Finnan. (Paper No. 06072005 at 3.)

For the reasons set forth below the rejection, respectfully is traversed.

Finnan is summarized above.

In making the rejection, the Examiner re-asserted his characterization of Finnan above. The Examiner acknowledged, however, that Finnan does not disclose "the claimed ratios of fat-soluble vitamin to the matrix." (Paper No. 06072005 at 3.)

To fill the acknowledged gap, the Examiner asserted that Example 10 of Finnan discloses "that vitamin E and the rest of the composition is roughly in equal proportions that is within the scope of claim 13 of instant application." (*Id.*) Moreover, the Examiner asserted that Finnan discloses "that a complete and stable emulsion formation is important for the entire edible oil (vitamin E) to be completely in the droplet form (col. 6, line 14) [and] that the molecular weight of gelatin also plays a role in the formulation of stable oil emulsion (col. 6, line 15-42)." (*Id.* at 3-4.)

The Examiner then concluded that "in the absence of any critically established with respect to the ratios of vitamin to matrix, it would have been obvious ... to optimize the amounts of gelatin and vitamin E so as to achieve complete

emulsification of Vitamin E in gelatin and spray dry the emulsion to produce a powder composition having a particle size of 74 to 250 microns without agglomeration.” (*Id.* at 4.)

The Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). “[T]o establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art.” MPEP § 2143.03 citing *In re Royka*, 180 USPQ 580 (CCPA 1974). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

The argument made above with regard to Finnan is equally applicable to the instant rejection. Finnan discloses particles sizes from 74,000 to 250,000 nanometers (74 to 250 microns). The claims recite a size of 80 to 120 nanometers. Accordingly, Finnan discloses particles sizes between about 600- and 3,100-times greater than those recited in the claims.

Finnan simple does not disclose or suggest the claimed droplet sizes. And, the rejection fails to identify where in Finnan such a limitation is disclosed or suggested. Accordingly, the rejection does not present a *prima facie* case for obviousness. For this reason, the rejection should be withdrawn.

Claims 1 and 3-6 were rejected under 35 USC § 103(a) as being unpatentable over Brenner *et al.*, U.S. Patent No. 3,971,852 in view of Finnan. (Paper No. 06072005 at 4.)

For the reasons set forth below the rejection, respectfully is traversed.

Brenner discloses "compositions, preferably in particulate form, comprising a cellular matrix having oil in the cells thereof in which the matrix comprises polysaccharide and polyhydroxy compounds in such proportions that the oil may constitute up to 80% by volume so stably held in the cells that the extractable oil is not substantially in excess of 5%." (Abstract.) Brenner further discloses that "when the composition is in particulate form it comprises generally spherical capsules, usually less than 400 microns in diameter." (Col. 1, lines 8-11.) Brenner discloses that in the preferred process produces an emulsion with oil droplet size of "about 0.5 to 5 micron[s] and spray dried droplets of about "fifty (50) microns." (Col. 10, lines 33-37.)

Finnan is summarized above.

In making the rejection, the Examiner asserted that Brenner discloses "a process of encapsulating an oil product in a particulate form comprising a polysaccharide form, comprising a polysaccharide matrix (col. 1, lines 12-20 and col. 10, lines 10-25). For particle size see col. 10, lines 25-47." (Paper No. 06072005 at 4.) The Examiner further asserted that Brenner discloses "polysaccharide gums for matrix composition ... in combination with polyhydroxy compounds [and] natural and synthetic oils ... to be encapsulated in the matrix." (*Id.*)

The Examiner acknowledged, however, that Brenner does not disclose "an oil soluble vitamin and the claimed particles sizes." (*Id.*) To fill the acknowledged gap, the Examiner relied on Finnan as disclosing "vitamin E oil or other edible oil encapsulation in gelatin, where the process of producing the powder formulation is similar to that of Brenner." (*Id.*)

The Examiner then concluded that "it would have been obvious ... to incorporate any oil, including vitamin oils of Finnan, for encapsulation in the [disclosure] of Brenner because both Finnan and Brenner are directed to the same field of endeavor (producing powder formulations of droplets of oils) and are directed to solving the same problem (stable encapsulation with high yield and low oil leakage), thus constituting analogous art. One of an ordinary skill in the art interested in producing feed or food product of vitamin E would have incorporated vitamin E oil of Finnan in place of the oils, in the [disclosure] of Brenner so as to successfully produce a high yield vitamin E powder composition." (*Id.*)

As noted above, to establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." MPEP § 2143.03. If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

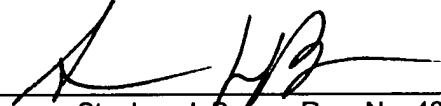
The argument made above with regard to Finnan is equally applicable to the instant rejection. Finnan discloses particles sizes from 74,000 to 250,000 nanometers (74 to 250 microns). The claims recite a size of 80 to 120 nanometers. Accordingly, Finnan discloses particles sizes between about 600- and 3,100-times greater than those recited in the claims.

Brenner discloses oil droplet sizes from 500 to 5,000 nanometers (0.5 to 5 microns) and a particle size of about 50,000 nanometers (50 microns). Accordingly, Brenner discloses a particle size about 600-times greater than those recited in the claims.

Brenner and Finnan, alone or in combination, simply do not disclose or suggest the claimed droplet sizes. And, the rejection fails to identify where in Brenner or Finnan such a limitation is disclosed or suggested. Accordingly, the rejection does not present a *prima facie* case for obviousness. For this reason, the rejection should be withdrawn.

Accordingly, for the reasons set forth above, withdrawal of the rejections and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on March 2, 2006.


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